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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,737	07/31/2003	Marvin S. Antelman	10514-024-999	6939

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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 10/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,737	ANTELMAN, MARVIN S.	
	Examiner	Art Unit	
	Frank I Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Terminal Disclaimer

The terminal disclaimer filed on 7/22/2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Pat. Nos. 6,258,385 and 6,485,755 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the tetrasilver tetroxide, does not reasonably provide enablement for all pharmaceutically acceptable derivatives or treatment, prevention or managment of all dermatological skin conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The nature of the invention:

The invention is directed to preventing, treating or managing one or more dermatological skin diseases in a patient's skin with tetrasilver tetroxide, or a pharmaceutically acceptable derivative, thereof, which is substantially free of added persulfate.

The state of the prior art and the predictability or lack thereof in the art:

Although the prior art of record shows the effectiveness of silver and tetrasilver tetroxide as an antimicrobial agent, the prior art of record does not appear to show that the silver or tetrasilver tetroxide is capable of treating,managing or preventing the enumerable possible dermatological skin diseases which would fall within the scope of claims

The amount of direction or guidance present and the presence or absence of working examples:

The Specification provides methods of administration and amounts but relatively few examples of effective treatment of a few dermatological conditions with tetrasilver tetroxide and does not appear to show prevention of any dermatological disease or condition or what derivatives of tetrasilver tetroxide would be suitable.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they claim undefined derivatives of tetrasilver tetroxide and any dermatological skin disease. As such, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to determine what other disease conditions would be effectively treated or managed, to determine that the dermatological skin diseases could be prevented and what derivatives would be effective for treatment, management or prevention of the dermatological skin diseases.

Examiner has duly considered Applicant's arguments but deems them unpersuasive. Applicant argues that pharmaceutically acceptable derivatives are well known in the art. However, the issue is not whether pharmaceutically derivatives in general are known in the art. The issue is whether Applicant's disclosure enables the full scope of Applicant's claims. Applicant has provide no evidence that one skilled in art would be able without undue experimentation determine a suitable pharmaceutical derivative of tetrasilver tetroxide. Applicant examples all involve the use of tetrasilver tetroxide and not a pharmaceutically acceptable derivative. Applicant has provide no evidence that one of ordinary skill in the art could arrive at a pharmaceutically derivative of tetrasilver tetroxide through routine screening or what would constitute routine screening. Arguments of counsel do not constitute evidence. For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement. See In re Knowlton, 183 USPQ 33, 37 (CCPA 1974); In re Wiseman, 201 USPQ 658 (CCPA 1979).

Claims 1-3,5-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3,5-24 contain the limitation "pharmaceutically acceptable derivative" which renders the claims indefinite as it is uncertain what is and what is included within the scope of said term and the Specification does not appear to adequately provide direction as to the same.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

The issue is not whether pharmaceutically acceptable derivatives are known in general, the issue is whether one of ordinary skill would reasonable understand what is include within the scope of the term in relation to tetrasilver tetroxide. Applicant's citation to other patents do not overcome the rejection herein. It is well settled that the prosecution of one patent application does not affect the prosecution of an unrelated application. *In re Wertheim*, 191 USPQ 90, 97 (CCPA 1976) (holding that "[i]t is immaterial in ex parte prosecution whether the same or similar have been allowed to others"). Applicant argues that one of ordinary skill in the art would recognize what is meant by pharmaceutically acceptable derivative because the Specification disclose the use of pharmaceutically acceptable salts of tetrasilver tetroxide. However, Applicant has made no showing that pharmaceutically acceptable derivative is limited to salts of tetrasilver tetroxide, as such, there is still the issue as to what is and what is not included with the scope of the term "pharmaceutically acceptable derivative."

Claim Rejections - 35 USC § 102/103

Examiner notes that the rejections under this section herein are not applicable to subject matter which was allowed in U.S. 6,258,385.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 7-9, 13, 14, 17, 20, 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Antelman (U.S. Pat, 5,571,520).

Antelman expressly discloses a method of treating athlete's foot and toenail fungus with solutions of tetrasilver tetroxide falling within the scope of applicant's claims (Column 4, lines 25-36). Athlete's foot and/or toenail fungus is associated with skin chafing, skin cracking, skin itch, and skin peeling.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See In re May, 197 USPQ 601, 607 (CCPA 1978). See also Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant does not provide evidence which shows that the claim limitation "adheres to skin" excludes the solution expressly disclosed by Antelman in that the level of adhesion is not defined in the claim. Clearly, when a foot is soaked in a solution and removed there will be solution on the foot until it evaporates or is physically removed. As such, Applicant has not shown that the limitation avoids the prior art. Further, Applicant's Specification indicates that the "substantially free" means that the claimed invention can include up to about 10% of added

persulfate. Applicant has provided no evidence that the amounts of persulfate added in the other examples cited by Applicant are greater than about10% of said examples.

Claims 1-3,5-24 are rejected under 35 U.S.C. 103(a) as obvious over Antelman (U.S. Pat. No. 5,571,520) in view of the acknowledge prior art, De Cuellar et al. (US Pat. 4,828,832), Fox, Jr., et al. (US Pat. 5,334,588), Dorland's (28th Ed. 1994), The Merck Manual (16th Ed. 1992), and Remington's (17th Ed. 1985).

Antelman teaches methods of treating dermatological conditions or diseases containing a molecular crystal device which is effective against bacteria, fungi, viruses and algae (Column 1, lines 44-47, Column 2, lines 38-68, Column 3, lines 1-20, Column 4, lines 25-36). It is taught that said device consists of a single crystal of tetrasilver tetroxide and that several hundred thousand trillion of these devices may be employed in concert for their bactericidal, fungicidal and algicidal properties and in various pharmaceutical formulations and therapies (Column 1, lines 44-52). A dermatological cream and douche containing 10 PPM, a solution containing 100 PPM, and a suspension of 25%, of said devices are taught (Column 2, lines 64-68, Column 3, lines 12-14, Column 4, lines 28, 29, 34). It is taught that amount of said devices contained in the formulations was determined by the minimal concentration of tetrasilver tetroxide required to inhibit the microorganism in nutrient broth (Column 2, lines 39-44).

Applicant acknowledges that it is known that tetrasilver tetroxide is effective against a wide spectrum of pathogens, including bacteria, algae, mold and the AIDS virus (Pg. 3, lines 22-36, Pg. 4).

De Cuellar et al. teach that silver oxide is effective against, pressure ulcers, chafing, impetigo, furunculosis sycosis of the beard, infected eczematous dermatitis, purulent acne, and postulous psoriasis, and that silver oxide compound avoids the side effects of silver sulfadizine therapy (Column 1, lines 50-68, Column 2, lines 1, 2, Column 3, lines 3-17, Column 4, lines 15-47).

Fox, Jr., et al. teach that silver compounds are effective against herpes simplex and herpes zoster and that silver oxide may be used in place of silver sulfadiazine (Column 2, lines 33-44, Column 3, lines 26-28, 31, 32).

Dorland's teaches that cold sores are caused by herpes simplex virus type1 and that shingles is caused by herpes zoster (Pgs. 351, 759-60).

The Merck Manual teaches that warts are caused by viruses (Pgs. 2426-27).

Remington's teaches that water-washable bases or emulsion bases, commonly referred to as creams, represent the most commonly used type of ointment bases and that emulsions bases are washable and easily removed from skin or clothing (Pg. 1574). It is taught that the oil phase of the emulsion base is typically contains petrolatum (Pg. 1574). It is taught that powders are encountered in almost every aspect of pharmacy, both in industry and in practice (Pg. 1585) Various methods of producing powders are taught, including bulk powders, such as douche powders and dusting powders (Pgs. 1585-1594, 1601). A method is taught of preparing dilutions of potent powdered drugs wherein the drug is intimately mixed with a suitable diluent (Pgs 1601, 1602).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the formulation of tetrasilver tetroxide dispersed in a petroleum jelly base or as a powder, and methods of treating eczema, psorisasis,dermatitis,ulcers, shingles, rashes, bedsores, cold sores, blisters, boils, herpes, acne, pimples and warts with tetrasilver tetroxide.

However, the prior art amply suggests the same as methods of preparing formulations, such as powders and creams, containing drugs, are well known in the art, and methods of treating dermatological conditions or diseases containing tetrasilver tetroxide are known in the art (Antelman, Column 1, lines 44-52, Column 2, lines 38-68, Column 3, lines 1-20, Column 4, lines 25-36; Specification, Pg. 1, lines 21-24; Remington's, Pgs. 1574, 1585-94, 1601, 1602). Furthermore, the prior art teaches equivalents, active ingredients, amounts and/or method steps which are close enough, overlap or are within the range and specific limitations of the claimed invention such that one of ordinary skill in the art would expect them to have the same properties (Antelman, Column 1, lines 44-52, Column 2, lines 38-68, Column 3, lines 1-20, Column 4, lines 25-36; Specification, Pg. 1, lines 21-24; De Cuellar et al., Column 1, lines 50-68, Column 2, lines 1, 2, Column 3, lines 3-17, Column 4, line 33; Fox, Jr., et al., Column 2, lines 33-44, Column 3, lines 26-28, 31, 32; Dorland's, Pgs. 351, 759-60, Remington's, Pgs. 1574, 1585-94, 1601, 1602). As such, it would have been well within the skill of one of ordinary skill in the art to employ various amounts of the active ingredients and method steps depending on end utility including amounts and method steps that fall within the scope of the claimed invention, because the same found in the prior art are fairly encompassed by or are close to the range and specific limitations of the claimed invention. Also, it would have been well within the skill of one of ordinary skill in the art arrive at the various amounts and/or ranges of tetrasilver tetroxide by optimization of the prior art conditions (Antelman, Column 2, lines 39-44). It would have been well within the skill of and one of ordinary skill in the art would have been motivated to treat cold sores, herpes, shingles and acne by applying tetrasilver tetroxide with the expectation that tetrasilver tetroxide would be effective as silver compounds, including silver oxide, are known to be effective in treating acne, herpes zoster and herpes simplex, and that warts are caused by viruses, therefore, it would have been expected that tetrasilver tetroxide, which is known to be a

broad spectrum biocide, would also be effective (De Cuellar et al., Column 1, lines 50-68, Column 2, lines 1, 2, Column 3, lines 3-17, Column 4, line 33; Fox, Jr., et al., Column 2, lines 33-44, Column 3, lines 26-28, 31, 32; Dorland's, Pgs. 351, 759-60; The Merck Index, pg. 2426-27). Also, one of ordinary skill in the art would have been motivated to employ a silver oxide compound, i.e. tetrasilver tetroxide, instead of silver sulfadiazine as tetrasilver tetroxide would be expected to have less side effects (De Cuellar et al., Column 1, lines 50-68, Column 2, lines 1, 2). Further, one of ordinary skill in the art would have been motivated to modify the prior art as above so as to employ a pharmaceutical formulation which is effective against a wide variety of dermatological pathogens and utilizes common industrial/pharmaceutical methods of preparing powders and creams (Antelman, Column 1, lines 44-52, Column 2, lines 38-68, Column 3, lines 1-20, Column 4, lines 25-36; Specification, Pg. 1, lines 21-24; De Cuellar et al., Column 1, lines 50-68, Column 2, lines 1, 2, Column 3, lines 3-17, Column 4, line 33; Fox, Jr., et al., Column 2, lines 33-44, Column 3, lines 26-28, 31, 32; Dorland's, Pgs. 351, 759-60; The Merck Index, pgs. 2426-37; Remington's, Pgs. 1574, 1585-94, 1601, 1602).

Examiner has duly considered Applicant's arguments but deems them unpersuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In the first instance, Applicant's Specification discloses that "substantially free" means that the claimed invention can include up to about 10% of added persulfate. Applicant has provided no evidence De Cuellar et al. discloses the use of persulfate or the use of persulfate which is not less than about 10%. The fact that DeCuellar et al. or Fox , Jr. et al. does not disclose tetrasilver tetroxide does not overcome the rejection as Applicant has not shown that pharmaceutically acceptable derivatives exclude silver oxide. Similarly, Applicant arguments with respect to the other references do not overcome the rejection as the rejection is based on the combination of references. As indicated above, the claimed invention need not be expressly suggested in any one or all of the references. The prior art rejection as a whole as indicated above discloses the use of tetrasilver tetroxide without the use of added persulfate, as such, the rejection herein is maintained

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC

October 4, 2004

S. MARK CLARDY
PATENT EXAMINER
GROUP 1209

1616